# "DESIGN AND DEVELOPMENT OF RAPIMELT TABLETS"

**SYNOPSIS**

SUBMITTED FOR REGISTRATION OF

THE DEGREE OF

**DOCTOR OF PHILOSOPHY**

IN THE SUBJECT

**PHARMACEUTICAL SCIENCES**

At

**SARDAR PATEL UNIVERSITY, BALAGHAT (M.P.)**

**By**

Mr Prashant Wake

M.Pharm.

**GUIDE**

Dr Rajesh Mujariya

M.Pharm., PhD

INSTITUTE OF PHARMACEUTICAL SCIENCE AND RESEARCH

SARDAR PATEL UNIVERSITY, BALAGHAT (M.P.),

2019-20

INDEX

| Sr. No. | Particulars | Page No. |
|---|---|---|
| 1. | Introduction | 3 |
| 2. | Literature Review | 8 |
| 3. | Aim and Objective | 10 |
| 4. | Plan of Work | 11 |
| 5. | Reference | 12 |

# 1. INTRODUCTION

## 1. Introduction

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis. For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Or dispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. Fast dissolving tablets are also called as mouth-dissolving tablets, melt-in mouth tablets, Orodispersible tablets, Rapimelts, porous tablets, quick dissolving etc. Fast dissolving tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva. The faster the drug into solution, quicker the absorption and onset of clinical effect. (Bhowmik D 2009).

## 1.1 Criteria for Rapimelts:

- The tablets should not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Be compatible with taste masking.
- Be portable without fragility concern.
- Have a pleasant mouth feel.
- Leave minimum or no residue in the mouth after oral administration.
- Exhibit low sensitive to environmental condition as temperature and humidity.
- Allow the manufacture of the tablet using conventional processing and packaging equipments at low cost. (Bhowmik D 2009).

## 1.2 Salient Feature of Rapimelts:

- Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric & psychiatric patients.
- No need of water to swallow the dosage form, which is highly convenient feature for
- patients who are traveling and do not have immediate access to water.
- Rapid dissolution and absorption of the drug, which will produce quick onset of action.
- Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is increased.
- Pregastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
- The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
- New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra rapid on set of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability. (Bhowmik D 2009).

## 1.3 Benefits of Rapimelts tablets

- Administered without water, anywhere, any time.
- Suitability for geriatric and pediatric patients, who experience difficulties in swallowing and for the other groups that may experience problems using conventional oral dosage form, due to being mentally ill, the developmentally disable and the

patients who are un-cooperative, or are on reduced liquid intake plans or are nauseated.

- Beneficial in cases such as motion sickness, suede episodes of allergic attack or coughing, where an ultra rapid on set of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability. (Bhowmik D 2009).

## 1.4 Limitations of Rapimelts Tablets

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly. (Bhowmik D 2009).

## 1.5 Common techniques for manufacturing of Rapimelts tablets are:

1. Lyophilization
2. Moulding
3. Direct Compression
4. Cotton Candy Process
5. Spray Drying
6. Sublimation
7. Mass Extrusion
8. Nanonization
9. Fast Dissolving Films (Nand P 2010).

**SUBLIMATION TECHNIQUE**

In the sublimation process, the tablet is formed with active ingredients and the recipients which are volatile in nature. After the compression of the tablets, the volatile ingredients are evaporated and the remnant is highly porous tablet which can be easily disintegrated. Inert solid ingredients such as urea, ammonium carbonate, ammonium bicarbonate, hexa methylene tetramine, camphor etc are added which can volatilize very easily. Highly porous

and compressed tablets were prepared by sublimation that was rapidly soluble in saliva. Mannitol and camphor were used as a tablet matrix material and subliming the material respectively. Sublimation of camphor was done in vacuum at 80 C for 30 minutes to develop pores in the tablets. Another technique describes use of water to produce fast dissolving tablets. Active ingredient and carbohydrates such as glucose or manitol were moistened with water (1-3% w/w) and compressed into tablets. Removal of water yielded highly porous tablets. (Nand P 2010).

**Patented Technologies For Fast Releasing Tablet Formation**:

**Zydis Technology**

Zydis was the first marketed technology developed by R.P.Scherer, Inc. for formation of new generation tablets. Zydis tablet is produced by lyophilizing or freeze-drying the drug in a matrix usually consisting of gelatin. The product is very light weight and fragile, which is dispensed in a special blister-packing. The preparation is also self-preserving because due to freeze drying, there is very little amount of water left in the drug for the attack of the microorganisms. The disintegration time of the tablets made by Zydis technology is few seconds.

**Durasolv technology**

The tablets made by this technology which was developed by CIMA labs, consist of a drug, fillers and the lubricants. The tablets are prepared by conventional tabletting equipment and have good rigidity. They can be packed in the conventional tabletting equipment and have good rigidity. This technology is good for tablets having low amount of active ingredients.

**Orasolv Technology**

CIMA labs developed this technology where the tablets are made by direct compression but with less of the pressure than the conventional DC. The active ingredient is taste masked and it also contains the effervescent disintegrators. The tablets produced are soft and friable and packaged in specially designed pick and place system.

**Wowtab technology**

Wowtab Technology is patented by Yamanouchi Pharmaceutical Co. where the word “WOW” means “without water”. It is the combination of low mouldability saccharides and high mouldability saccharides used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet.

**Flashtab technology**

The tablet prepared by this technology was patented by Prographarm laboratories. It consists of active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like coacervation, microencapsulation, and extrusion spheronisation. (Nand P 2010).

# 2. LITERATURE REVIEW

**2.1 Bhowmik D *et al* (2009)** was studied that the Fast dissolving Tablets was disintegrating and/or dissolve rapidly in the saliva without the need for water. Some tablets was designed to dissolve in saliva remarkably fast, within a few seconds, and was true fast-dissolving tablets. Others contain agents to enhance the rate of tablet disintegration in the oral cavity, and are more appropriately termed fast-disintegrating tablets, as they may take up to a minute to completely disintegrate. Oral delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, most convenient and most economical method of drug delivery having the highest patient compliance.

**2.2 Nand P *et al* (2010)** was studied the Mouth Dissolving Tablets was one of the fruitful results of these technological advancements. MD tablets play a major role in improving the patient's compliance. They rapidly disintegrate in the saliva hence obviating the need of the water. With the increasing incidences of non-compliance among the patients, Mouth dissolving tablets are the perfect answer to all these problems. A variety of drugs can be administered in the form of MD tablets as they give the advantage of the liquid medication in the solid preparation.

**2.3 Singh H *et al* (2011)** was studied that to enhance the solubility of Carvedilol by solid dispersion method and formulate a mouth dissolving tablet. Drugs was more frequently taken by oral administration. The solubility of Carvedilol enhanced with different ratios of PVP by the solvent evaporation method .In-vitro release profile of solid dispersion obtained in SGF with out enzymes and Ph 6.8 phosphate buffer indicate that 100% drug release found within 20 min. These solid dispersion was directly compressed into tablets using crospovidone, sodium starch glycol ate, croscarmellose sodium and polacrilin potassium in different concentrations as a superdisintgrants. The prepared tablets containing the solid dispersion of Carvedilol having sufficient strength of 2.5-4 kg/cm2. The disintegranted in the oral cavity with in 21 sec. contain crospovidone (5%) as super disintegrant.

**2.4 BEDI N *et al* (2009)** was studied to undertaken with a view to develop mouth-dissolving tablets of oxcarbazepine, which offers a new range of product having desired characteristics and intended benefits. In this study, the mouth dissolving tablets were prepared using two different technologies, direct compression method and solid dispersion technology. Tablets produced by direct compression method contain crospovidone as a superdisintegrant and aspartame as a sweetener. Solid dispersions of oxcarbazepine with polyvinylpyrrolidone K-30 and polyethylene glycol 6000 in different weight ratios were prepared with a view to increase its water solubility. Oxcarbazepine solid dispersions with polyvinylpyrrolidone K-30 in 1:2 ratios of drug: carrier showed maximum drug release and hence, compressed along with other excipients into mouth dissolving tablet. The results compared for both the technologies showed that the oxcarbazepine tablets prepared using solid dispersion technology was found to have good technological properties and satisfying and reproducible drug dissolution profiles. Moreover the drug release was found to be comparable to the marketed dispersible tablet.

**2.5 BHARDWAJ S *et al* (2010)** was studied to prepare fast dissolving tablets of the drug using various super disintegrates sodium starch glycolate following by direct compression technique. The tablets was evaluated for hardness, friability, weight variation, disintegration time, water absorption ratio and wetting time, in vitro dissolution studies. All the formulation showed disintegration time in range of 12.2 to 27.5 second along with rapid in vitro dissolution. It was concluded that the fast dissolving tablets of the poor soluble drug can be made by direct compression technique using selective super disintegrantes showing enhanced dissolution, taste masking and hence better patient compliance and effective therapy.

# 3. AIM AND OBJECTIVE

## 3.1 Aim

To design and develop Rapimelts tablets.

## 3.2 Objective

- To formulate Rapimelts tablet with pleasant taste and better mouth feel.
- To get rapid onset of action.
- To improve Bioavailability.

# 4. PLAN OF WORK

4.1. Literature survey

4.2. Procurement of Drugs and Excipients

4.3. Preformulation study

4.4. Formulation of Rapimelt tablets

4.6. Evaluation of Rapimelt tablets

a) Tablet thickness
b) Hardness
c) Wetting time
d) Weight variation
e) Friability test
f) Assay for drug content
g) Disintegration time
h) *In-vitro* release Study
i) Stability Studies

4.7 Results and Discussion

# 5. REFERENCES

Bedi N, Khurana S, Kalia A, 2009, "Formulation and Evaluation of Mouth Dissolving Tablets Of Oxcarbazepine", *International Journal of Pharmacy and Pharmaceutical Sciences,* 1(1):12-23.

Bhardwaj S, Jain V, Jat RC, Mangal A, Jai S, 2010, "Formulation and evaluation of fast dissolving tablet of aceclofenac", *International Journal of Drug Delivery,* 2:93-97.

Debjit Bhowmik, Chiranjib.B, Krishnakanth, Pankaj, R.Margret Chandira, 2009, "Fast Dissolving Tablet: An Overview", *Journal of Chemical and Pharmaceutical Research,* 1(1): 163-177.

Nand P, Vashist N, Anand A, Sushma Drabu, 2010, "Mouth Dissolving Tablets- A Novel drug delivery system", *International Journal of Applied Biology and Pharmaceutical Technology,* 1(3):1-7.

Swatantra Ku. Mishra, Rakesh Varma and Sandeep Singh Parihar, 2011, "Formulation and Evaluation of Mouth dissolving tablets of carvedilol", *International Journal of Pharma and Bio Sciences,* 2(1):232-239.

**(Mr Prashant Wake)**
**M.Pharm.**
**Research Scholar**

**Dr D R Mundhada**
**M.Pharm., PhD**
**Research Co-Guide**

**(Dr Rajesh Mujariya)**
**M.Pharm., PhD**
**Research Guide**